



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,793	11/12/2003	Charles D. Swerdlow	SWD200DIV	7163

24339 7590 01/03/2007
JOEL D. SKINNER, JR.
SKINNER AND ASSOCIATES
212 COMMERCIAL ST.
HUDSON, WI 54016

EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
----------	--------------

3762

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
2 MONTHS	01/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/706,793

Applicant(s)

SWERDLOW ET AL

Examiner

George R. Evanisko

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Rep.,

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 116-136 is/are pending in the application.
- 4a) Of the above claim(s) 116, 117 and 136 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 118-135 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 116, drawn to a controller apparatus for determining cardiac shock strength, classified in class 607, subclass 62.
- II. Claim 117, drawn to an apparatus for delivering cardiac shocks, classified in class 607, subclass 28.
- III. Claims 118-135, drawn to an apparatus for inducing fibrillation, classified in class 607, subclass 8.
- IV. Claim 136, drawn to a method for determining cardiac shock strength, classified in class 607, subclass 62.

The inventions are distinct, each from the other because of the following reasons:

Inventions IV and (I, II, and III) are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process not requiring sensing a change with respect to a T wave that is an extreme absolute value but just searching for an upslope of a T wave. In addition, the process as claimed can be practiced by another and materially different apparatus not requiring the memory unit and controller, but by hardwired circuitry and physician assistance.

Inventions II and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination as claimed does not require the sensor to sense fibrillation or a change in the T wave. The subcombination has separate utility such as not requiring electrodes for delivering shocks, but used solely as a sensing system to calculate shock strength.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Inventions III and (I and II) are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require the controller providing test shock and time

Art Unit: 3762

relating to change in the T wave and determine the cardiac shock strength or the electrodes to also include sensing. The subcombination has separate utility such as a system not requiring memory to store pacing cycle length, initial shock strength and other values, but by allowing the physician to enter these values before operation.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Joel Skinner on 12/14/06 a provisional election was made without traverse to prosecute the invention of group III, claims 118-135. Affirmation of this election must be made by applicant in replying to this Office action. Claims 116, 117, and 136 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

Claims 118-135 are objected to because of the following informalities listed below. Appropriate correction is required.

In claim 118, line 11, “the maximum derivative of the T-wave” has not been previously set forth and requires an element to determine the maximum derivative. It is suggested to use “a maximum derivative...” and to include either the timer or controller with the function of determining the maximum derivative, such as “wherein said controller determines the maximum derivative of the T wave from said sensor”. In line 15, “such as” does not specifically set forth the limits of the claim because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). It is suggested to state “, said programmable values comprising...”. In lines 18 and 20, “whereby” should be “wherein” since it has been held that the functional “whereby” statement does not define any structure and accordingly can not serve to distinguish. *In re Mason*, 114 USPQ 127, 44 CCPA 937 (1957). The examiner has interpreted the “whereby” to be “wherein” since the claim further defines limitations that are not a result of the previous structure and therefore the claim should be amended accordingly. In paragraph “(d)”, the paragraph is not stating what element is performing these functions. It is

Art Unit: 3762

suggested to state “wherein said controller is programmed to cause...” and then further correct paragraphs (i)-(iv). In line 25, it is suggested to delete the “,” and insert “by”.

In claims 119-121, the claims are not stating what element is performing the operations/functions in the claims. It is suggested to state the controller is performing those operations.

In claim 121, “an implantable cardioverter defibrillator” should be “the...defibrillator” since it is used in claim 118.

In claim 123, “an electrogram” should be something similar to “the electrical activity of the heart” to relate it to the sensor sensing the electrical activity.

In claim 126, it “consists” should be “comprising” since it is open ended and since claim 132 is not an implanted electrode.

In claims 126-131, “implanted” should be “implantable” since implanted is more like a method step and apparatus claims can not claim connection to the body.

In claim 133, the claim should relate to where in the system this function is performed, such as after the other functions are performed from claim 118, since claim 118 sets forth that multiple shock strengths are used (and not “only one shock strength” as set forth in claim 133).

In claim 134, “the energy level” has not previously been set forth and should be related to an element in claim 133.

Allowable Subject Matter

The following is a statement of reasons for the indication of allowable subject matter: The subject matter of the independent claim could either not be found or was not suggested in the prior art. The subject matter not found was the ICD for determining and delivering an

Art Unit: 3762

optimal programmed first shock strength based on the upper limit of vulnerability comprising providing a series of shock times timed relative to the maximum derivative of the T-wave and decreasing the shock strength by a strength decrement and delivering test shocks at a sequence of intervals if the heart does not defibrillate, in combination with the other elements and functions in the claims.

The closest prior art of Bach, Jr. et al uses a decreasing shock strength to determine the ULV and uses T waves to shock the heart, but does not provide several elements, such as a series of shock times timed relative to the maximum derivative of the T-wave.

Conclusion

This application is in condition for allowance except for the following formal matters:

Cancellation of non-elected claims and correction of claim objections.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.


A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


George R Evanisko
Primary Examiner
Art Unit 3762

12/23/06

GRE
December 23, 2006